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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,511	09/29/2000	Ludwig Wolf JR.	112754-019	9637

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/02/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,511

Applicant(s)

Wolf et al.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 18, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30, 32, 34, 36, and 38-51 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30, 32, 34, 36, and 38-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment filed 7/18/02 is acknowledged. Claims 28-30, 32, 34, 36, 38-51 are pending and are considered on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-30, 32, 34, 38-47, 49, 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,207,107 [A] the reasons as stated in the last Office action and the further reasons below.

US 6,207,107, claims 3-8 are directed to a method where the container which holds the body fluid has a interior constructed from a non-PVC material (claim 7) and the tubing which holds the MB solution has an inner surface of a non-PVC material (claim 6), mixing the body fluid and the MB solution and irradiating the mixture.

It is noted that applicants intend to file a Terminal Disclaimer. In the absence of this document, the rejection is maintained.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 28-30, 32, 24, 26, 38-51 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 40 are directed to inactivating viruses in "a body fluid". However, the specification defines "body fluid" as red cells, white cell, bone marrow, platelets (p. 6, l. 1-5), and even "internal organs" (p. 8, l. 10). Clearly, these materials are not "fluids" as defined by Webster's New World Dictionary [U]. Although the definition in the specification includes these non-fluid cells and organs, applicants cannot define a term in opposition to a generally accepted definition. In re Hill 73 USPQ 482 (CCPA 1970).

Claim 40 is vague and indefinite in the recitation "at least one port extending from the container". From the dictionary definition it is apparent that a port is an opening. It is unclear how it would "extend" from the container. Also the meaning of "controlled access" is uncertain in this context. How is access "controlled"?

Response to Arguments

Applicant appears to argue that an organ suspended in medium falls under the definition of "body fluid". Clearly this is not the generally accepted meaning of "body fluid". Amendment of the claim to recite "blood, or blood component" instead of "body fluid" would eliminate this argument. It is apparent that blood is the only organ that can be considered to be "fluid". No objective, scientific definition has been supplied which shows that, for example, an excised liver in DMEM can be considered by a person ordinarily skilled in the art, to be a "body fluid".

Common sense alone would negate this interpretation which applicant continues to urge. Further, while blood can be considered to be a body fluid, once the plasma is removed, which is how red cell concentrates are produced, the red cells can no longer be considered to be a body fluid. Likewise, platelets, lymphocytes and other formed elements of blood cannot be considered to be a body fluid. Whole blood is body fluid, while a red cell concentrate, a platelet suspension or an organ in Ringer's medium are not. It is suggested that replacement of "body fluid" with "blood or a blood component" at each occurrence would resolve this issue.

NEW MATTER

Claims 28-30, 32, 34, 36, 38, 39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "sealed" containers, has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor is there a specific example of the new limitation which would show possession of the concept of the use of "sealed" containers, as there is no exemplification contained in the specification.

This is a matter of written description, **not a question of what one of skill in the art would or would not have known**. The material within the four corners of the as-filed specification must lead to the concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of this phrase is considered to be the insertion of new matter for the above reasons.

Pointing to the passage where this limitation is recited with reference to both methylene blue and body fluid containers would overcome the rejection.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant contends that the containers "of course... have to be sealed as one skilled in the art would know." This is a matter of written description, **not a question of what one of skill in the art would or would not have known**. The material within the four corners of the as-filed specification must lead to the concept. If it does not, the material is new matter.

With respect to the Optipak^R system disclosed in U.S. Patent No. 4,608,178, it is not clear which portion of the patent is being referenced by applicants. Also it is unclear that this patent was incorporated by reference, but merely was used as an example.

In Figure 2, it is unclear which "container" is deemed sealed in the context of the instantly claimed invention.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 40-42, 44, 45, 49 are/remain rejected under 35 U.S.C. 102(e) as being anticipated by US 5,445,629 [B] or by US 6,207,107 [A] for the reasons as stated in the last Office action and the further reasons below.

US 5,445,629 discloses a method of treating blood or blood components comprising providing methylene blue in a plastic container which has an inner liner of a non-PVC, plastic material (col. 5, l. 15); providing blood in a plastic container which may, in an embodiment, be PVC (col. 4, l. 3); mixing blood and photoactive agent (methylene blue) and irradiating (col. 3, l. 10).

US 6,207,107 discloses in one embodiment, placing MB in a container which has an inner liner of SBS, polyester, PVA, polypropylene and an outer layer of PVC or the entire container may be PVC free, adding blood and irradiating. In another embodiment, the MB is in a container (tube) which has at least an inner layer which is PVC-free and is connected to a bag into which the blood is infused, mixing the BM and the blood and then irradiating the mixture.

Leaching is considered to be an inherent, passive action when methylene blue is placed in contact with plastic in the absence of evidence to the contrary.

"To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *id.*; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See

In re King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See *Titanium Metals*, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id.* at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); *Verdegaal Bros.*, 814 F.2d at 633.

This court's decision in *Titanium Metals* illustrates these principles. See *Titanium Metals*, 778 F.2d at 775. In *Titanium Metals*, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals*, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id.* at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See *Atlas Powder Co. v. IRECO Inc.* 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations.

Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the leaching of MB flows from the contact of a solution of MB with plastic. Please note that only one molecule of MB need migrate into the plastic to fulfill the claim limitation.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' assertion that the rejections are improper as a matter of law and fact is not will taken. The critical date for removal of 102(e) rejections when there is a common assignee is November 29, 2000 unless the application was voluntarily published. This does not appear to be the case here.

With regard to the addition of a limitation regarding a "port" and its alleged absence in the references, it is noted that the dictionary definition of "port" is *an opening (as in a valve seat or valve face) for intake or exhaust of a fluid; b : the area of opening in a cylinder face of a passageway for the working fluid in an engine; also : such a passageway*". It is apparent that the reference containers both have at least one port connected to a hose.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 103

Claims 40-47, 49 and 51 are rejected under 35 U.S.C. § 103 as being unpatentable over US 5,445,629 [B] and Rock *et al.* [V] or Walvik *et al.* [D4] for the reasons as stated in the last Office action and the further reasons below.

The claims are drawn to a method of viral inactivation comprising providing a body fluid in a first container and methylene blue in a second container both of which have an inner surface made of a non-polyvinyl chloride material, mixing the two and irradiating the mixture under "no-flow" conditions.

US 5,445,629 has been explained above. This reference lacks the explicit disclosure of the use of a container in which the mixture is formed which lacks PVC plastic.

Rock *et al.* disclose blood bags made of polyolefin or PVC. Polyolefin bags are used for platelets (Page 496, col. 2).

Wallvik *et al.* disclose bags made of either PVC or polyolefin used to contain blood components.

The use of either a PVC containing container or a PVC-free container to mix the blood or blood components and the methylene blue would have been obvious when the disclosure of '629 (col. 3, l. 68) is taken, where it is stated that depending on the specific (blood) components to be stored, certain plastics may be more desirable was taken with [U], which discloses that polyolefin is a suitable plastic material for the storage of platelets.

Whether the blood or blood component is added to the MB or the MB is added to the blood or blood component appears to be an element which is well within the purview of one of ordinary skill in the art absent any evidence of criticality. Selection of any order of adding ingredients is *prima facie* obvious (MPEP 2144.04C).

With regard to the length of time of irradiation, the reference teaches that the irradiation should activate the MB in the container and inactivate any pathogens without stipulating any length of time. Thus, one of ordinary skill in the art, knowing the desired end point (inactivation of pathogens) may irradiate any desired length of time in order to achieve this end point in the absence of evidence of criticality.

It would have been obvious to substitute any containers made of any material known in the art to contain the "body fluid" in the method of US '629 which teaches that the type of plastic container depends on the component to be stored when taken with Wallvik *et al.* or Rock *et al.* each disclosing a container made from polyolefin to store platelets or red cells, respectively. A polyolefin container has an inner surface which is not a PVC material.

It would have been obvious to add one component to the other in whatever art appropriate container and in whatever order one of skill in the art wished in the absence of evidence to the contrary regarding the criticality of such an addition or container.

Claims 28-30, 32, 34, 39-47, 49, 51 are rejected under 35 U.S.C. § 103 as being unpatentable over US 6,207,107 [A].

The claims are directed to a method of inactivating pathogens comprising storing MB in a separate, sterile container (1) having an inner surface which is PVC-free plastic, storing a body fluid in a separate, sterile container (2) having an inner surface which is PVC-free plastic and other parts of the container (2) have portions made of PVC; mixing the two and irradiating.

US 6,207,107 discloses in one embodiment, placing MB in a container which has an inner liner of SBS, polyester, PVA, polypropylene and an outer layer of PVC or the entire container may be PVC free, adding blood from another container and irradiating. In another embodiment, the MB is in a container (tube) which has at least an inner layer which is PVC-free and is connected to a bag into which the blood is infused, mixing the BM and the blood and then irradiating the mixture.

It would have been obvious to contain the body fluid in the method of US 6,207,107, particularly in the first embodiment in a container which has an inner layer of SBS, polyester, PVA, polypropylene and an outer layer of PVC because this type of container is taught in the prior art disclosure of '107. In the absence of criticality, one of skill in the art may freely use any known, art appropriate container to store blood. The blood may then be transferred to the second container in which the MB is stored, which container also has an inner layer of PVC-free material.

It would have been obvious to add one component to the other in whatever art appropriate container and in whatever order one of skill in the art wished in the absence of evidence to the contrary regarding the criticality of such an addition or container.

With regard to the length of time of irradiation, the reference teaches that the irradiation should activate the MB in the container and inactivate any pathogens without stipulating any length of time. Thus, one of ordinary skill in the art, knowing the desired end point (inactivation of pathogens) may irradiate any desired length of time in order to achieve this end point in the absence of evidence of criticality.

One of skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' assertion that the rejections are improper as a matter of law and fact is not will taken. The critical date for removal of 103/102(e) rejections when there is a common assignee is November 29, 2000 unless the application was voluntarily published. This does not appear to be the case here.

Therefore the rejections are deemed proper and are adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651